

REMARKS

Claim 19 has been cancelled, without prejudice.

Claims 1-18 and 20-22 have been amended to conform with U.S. practice and for clarity. Support for these amendments are found in the specification at, for example, pages 3-7.

Claims 1 and 6 also have been amended to correct minor informalities.

Claims 5, 7, 8, 9, 12, 13, 14, and 16 have been amended to correct improper multiple dependencies.

The optional component of claim 10 has been cancelled and presented in the form of new claim 23.

The specification has also been amended to present an Abstract on a separate sheet as required by 37 CFR § 1.72(b). Support for this amendment is found, for example, in the underlying International Application Number PCT/EP97/06103 (front page), the specification at pages 3-5 and original claim 1.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments are respectfully solicited.

Objections

The Examiner objected to claims 5, 7, 8, 9, 12, 13, 14, and 16 under 37 CFR § 1.75(c) as being in improper form. (Office Action dated 4/21/05 at p. 2).

With a view towards furthering prosecution, claims 5, 7, 8, 9, 12, 13, 14, and 16 have been amended to correct any improper multiple dependency. In view of the foregoing, the objection of claims 5, 7, 8, 9, 12, 13, 14, and 16 is rendered moot. Accordingly, withdrawal of the objection is respectfully requested.

The Examiner also objected to the specification as having an improper abstract. (*Id.* at 3).

We note that the underlying International Application Number PCT/EP97/06103, contained an Abstract. For the convenience of the Examiner and to further prosecution, the specification has been amended to present an Abstract with an Abstract on a separate sheet as required by 37 CFR § 1.72(b). Accordingly, withdrawal of the objection is respectfully requested.

The Examiner also objected to the "disclosure ... because of the following formalities ... "[w]ords 'selected from compounds' in claim 1, lines 8-9 should be replaced with -- which is one of the --," and the "[h]yphen in claim 1 line 9 and dash in line 10 should be deleted." (*Id.*)

With a view towards furthering prosecution, claim 1 has been amended to conform with U.S. practice and for clarity. In view of these amendments, it is believed that the objections of claim 1 are rendered moot. Accordingly, withdrawal of the objections are respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph and 35 U.S.C. § 101

Claims 17-19 were rejected under 35 U.S.C. § 112, second paragraph. (*Id.* at 2). In making the rejection, the Examiner asserted that "[c]laims 17-19 provide for the use of the film made from [the] (claimed) composition, but, since the claim does not set forth steps involved in the method/process, it is unclear what method/process applicant is intending to encompass." (*Id.*)

Claims 17-19 were also rejected under 35 U.S.C. § 101. In making that rejection, the Examiner asserted that "the claimed recitation of a use, without setting

forth any steps involved in the process, results in an improper definition of a process" (*Id.*).

With a view towards furthering prosecution, claims 17 and 18 have been amended to recite consumer products and compositions comprising the film of claim 16, and claim 19 has been cancelled. In view of the foregoing, the rejections of claims 17-19 are rendered moot. Accordingly, withdrawal of the rejections is respectfully requested.

Claims 1, 2, and 6 were also rejected under 35 U.S.C. § 112, second paragraph. (*Id.* at 2-3).

In making the rejection of claim 6, the Examiner asserted that "[c]laim 6 recites words 'on average' in [] parenthesis," and "[i]t is not known if the matter in the parenthesis is or is not encompassed by the scope of this claim." (*Id.* at 3).

The Examiner further asserted that "[c]laim 1 recites matter in parenthesis in lines 12-13," and "[c]laim 1 is further indefinite since it is not known how low [] the value of pK [can] be and how high [the] HLB can be." (*Id.*)

The Examiner further asserted that "[c]laim 2 is indefinite in reciting '3 or more carbon atoms' and '2 or more alcohol groups' because one cannot know[] precisely how many carbon atoms or how many alcohol groups are envisioned." (*Id.*)

Initially, we note that claim 6 has been amended to remove the parenthesis from "on average." In view of the foregoing, the rejection of claim 6 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 1 has also been amended to remove the parenthesis. In view of the foregoing, the rejection of claim 1 with respect to the parenthesis is moot.

We respectfully traverse the rest of the rejection of claim 1 with respect to the assertion that the lack of recitation in the claim of a lower limit for the pK and a higher limit for the HLB renders the claim indefinite.

As is well settled, all that is required to comply with 35 U.S.C. § 112, second paragraph, is that the metes and bounds of what is claimed be determinable with a reasonable degree of precision and particularity. *Ex parte Wu*, 10 USPQ2d 2031, 2033 (BPAI 1989). Here, as of the filing date of the present application, the state of the art with respect to the use of biodegradable polymeric compositions was well developed. Accordingly, it is submitted that the scope of claim 1 would have readily been ascertainable to one skilled in the art when the claim is read in light of the description portion of the specification and the state of the art as of the filing date of the present application.

The Examiner appeared to express concern over the fact that the low end for the pK value and the high end for the HLB are not recited in the claim. *Id.* The legal standard for definiteness, however, is whether a claim reasonably apprises those of skill in the art of its scope. *In re Warmerdam*, 31 USPQ 2d 1754, 1759 (Fed. Cir. 1994). Here, claim 1 meets that standard. The claim appraises **what** the invention is and 35 U.S.C. § 112, second paragraph, does not require that the claims recite every detail of **how** it can or should be done. It is submitted that this rejection, under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claim 1 is not indefinite with reference to a HLB value greater than 8. From the formula on page 5, line 9 of the specification, it is clear that the HLB value cannot, in any case, be higher than 20. The formula recites that $HLB = 20 \times M_h/M$, and

at the utmost, M_h/M is equal to 1. M_h is the molecular mass of the hydrophilic fraction of the molecule, and M is the total molecular mass.

As for the lower than 4.5 value of pK in claim 1, the value of pK is inherent in the definition of pK. In other words, pK is $\log K$, where K corresponds to the dissociation constant of the acid. The lower the value for pK, the stronger the acid is. Accordingly, the condition in claim 1 that the pK must be lower than 4.5 indicates that the acid, which forms the ester, must be stronger than an acid having a pK of 4.5. For example, acetic acid has a pK of about 4.75, and the limitation in claim 1, therefore, requires that the acid forming the ester be stronger than acetic acid.

Notwithstanding the forgoing, the Examiner is placing great weight on the *breadth* of the claim. That is legal error because the breadth of a claim is not a proper basis of rejection under §112, second paragraph. *In re Miller*, 169 USPQ 597 (CCPA 1971); MPEP § 2713.04.

As noted above, to reject a claim under the second paragraph of 35 U.S.C. § 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Wu*, 10 USPQ2d at 2033. This, the Examiner has not done. The Examiner has not made any factual determination that establishes that one of ordinary skill in the art would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims based upon the terms "lower" and "greater" as used in claim 1. Relative terms are not *per se* indefinite. And merely

characterizing them as such does not satisfy the Examiner's burden. For this additional reason, the rejection cannot stand and should be withdrawn.

With respect to claim 2, the rejection suffers from the same infirmity as the rejection of claim 1. Breadth is not indefiniteness. *Miller*, 169 USPQ at 597; MPEP § 2713.04. The legal standard for definiteness is whether a claim reasonably apprises those of skill in the art of its scope. *Warmerdam*, 31 USPQ2d at 1759. Here, there is no question as to the scope of the claim. For this reason alone, the rejection should be withdrawn.

Further, we note that by indicating the HLB value, which takes into account the hydrophilic fraction of the ester molecule, one skilled in the art would indeed be able to ascertain with a reasonable degree of precision and particularity the number of carbon atoms and alcohol groups in the claimed polyol. For this additional reason, it is respectfully submitted that rejection should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1-4, 6, 10, 11, 15, and 17-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Krishnan *et al.*, WO 95/24447 ("Krishnan"). (Office Action dated 04/21/05 at 4). For the reasons set forth below, the rejection is respectfully traversed.

Krishnan discloses compatibilized blends of biodegradable hydrophobic polyester, unmodified starch or other similar polysaccharide, other biodegradable polymers, plasticizers, and additives. (Abstract). These blends are produced in the absence of water. The presence of water is considered detrimental by Krishnan because the effect of the reduced melt elongation and strength is greater than the

enhancement of the interfacial adhesion that the presence of water could promote (page 18, lines 1-9): "The presence of water is deleterious ... in melt elongation and strength."

In making the rejection, the Examiner asserted that in Krishnan "[t]he polymer forms a continuous phase while starch forms a discontinuous one. A preferred biodegradable polymer is poly (E-caprolactone) (p. 7 line 20). Organic plasticizers, such as esters are included in the blend (p. 15, lines 21-30). Compatibilizers are also used (p. 13, lines 18-35). Also included in the blend may be certain additives that function as binders by complexing with starch (p. 19, lines 10-16). They include monoglycerides." (Office Action dated 04/21/05 at 4).

The Examiner acknowledged, however, that "Krishnan does not mention the (claimed) dissociation constant pK and hydrophilic lipophilic balance index value HLB of the ester." (*Id.*) The Examiner asserted, however, that "[s]ince Krishnan broadly teaches the (claimed) glycerides, it is reasonable to assume that [the] glycerides of Krishnan possess these properties," and "[t]herefore it would have been obvious to follow teachings of Krishnan and arrive at [the] instant invention." (*Id.* at 5).

Initially, we note that the Examiner bears the burden of setting forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *Glaug*, 62 USPQ2d at 1152. Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or

suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

Claim 1 recites an interfacial agent which is an ester having an HLB greater than 8, which ester is obtained from (1) a polyol, (2) a monocarboxylic acid, or (3) a polycarboxylic acid, each of which have a pK lower than 4.5.

Krishnan does not disclose or suggest the interfacial agents of the claimed invention. The Examiner refers to "organic plasticizers" cited by Krishnan, which include glycerol monoacetate, diacetate, and triacetate. (See page 15, lines 21-30). However, since acetic acid has a pK higher than 4.5 (namely 4.75), the cited glycerol esters are clearly outside the scope of claim 1. Also, the binders to which the Examiner refers, cited on page 19, lines 10-16 of Krishnan, include glycerol monostearate and glycerol monopalmitate, which have a HLB of about 3.8 (see Exhibit 1), and are therefore lower than the minimum value (HLB > 8) required by the presently claimed invention. Furthermore, stearic acid and palmitic acid are weak acids having a pK higher than 4.5. Clearly such binders do not fall within the scope of the claimed invention and do not suggest the specific interfacial agent of the claimed invention. For this reason alone, it is respectfully submitted that rejection should be withdrawn.

Krishnan also discloses the use of decaglycerol tetraoleate as a stretching agent, which improves the tensile elongation of the blend materials. (See page 19, lines 23-35). Decaglycerol tetraoleate has a HLB of 6.2 and is outside the scope of the claimed interfacial agents. (See Exhibit 2). According to Krishnan, compositions without decaglycerol tetraoleate are brittle and have a poor elongation at break. (See page 19, lines 28-29).

Therefore, Krishnan not only fails to disclose or suggest the dissociation constant pK and the HLB value for the claimed interfacial agents, but also fails to disclose or suggest interfacial agents exhibiting properties of the claimed compositions (*i.e.*, capable of maintaining high mechanical properties under conditions of low humidity). For this additional reason, it is respectfully submitted that rejection should be withdrawn.

The interfacial agents according to the claimed invention are specifically designed to achieve compositions having a fine microstructure of starch, with a size of the dispersed starch particles less than 1 μm for more than 80%. (See page 7, lines 7-16). The microstructure allows the production of films, which still retain good tensile and tear strength properties after washing with water. (See page 7, last full paragraph). Thus, contrary to the Examiner's assertion regarding criticality (see p. 5), the application clearly identifies the need for the pK and HLB parameters recited in the claims.

Even with the use of decaglycerol tetraoleate, the blends disclosed by Krishnan do not achieve the fine microdispersion of starch achieved by the claimed invention. Example 2 of Krishnan relates to the use of decaglycerol tetraoleate, and the structure of the resulting blend is shown in Figure 1. In Figure 1, starch particles are visible, which have a size of about 10 μm . (See page 22, Example 2 and Figure 1).

This is because Krishnan is based on principles, which are quite different from that of the claimed invention. Krishnan requires the use of decaglycerol tetraoleate and also the use of a starch, which has been pre-dried, before being blended, to a moisture content of less than 1% by weight and preferably between 0.5% and 1.0% by weight. In Krishnan, the presence of water in greater amounts is

considered detrimental, since the effect of the reduced melt elongation and strength is greater than the enhancement of the interfacial adhesion that the presence of water could promote. (See page 18, lines 1-9). By contrast, the esters recited in claim 1 are water soluble (see, e.g., Specification at p. 5).

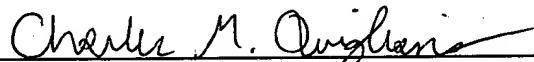
Thus, the Krishnan compositions are non-analogous to the presently recited compositions. Thus, for this further reason, it is respectfully submitted that the rejection should be withdrawn.

We further note that the rejection treats all the claims as standing or falling with claim 1. The rejection, however fails to account for the further elements recited in the dependent claims. For example, the Examiner failed to make any factual determinations regarding whether the starch disclosed in Krishnan has a microstructure in which at least 80% of the particles have dimensions smaller than 1 μ m as recited in claim 20 or whether the thermoplastic polymer is obtained by one of the reactions recited in claim 14. For this additional reason the rejection is insufficient as a matter of law and should be withdrawn.

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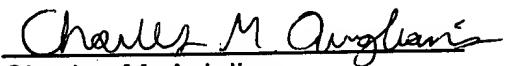
For the reasons set forth above, entry of the amendments, withdrawal of the rejections and objections, and allowance of all claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on August 22, 2005.



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